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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,589	03/29/2004	Eric Tomasetti	TR-6132 (BXTC 4021)	2100
7590 04/23/2009				
Mr. Joseph B. Barrett Baxter Healthcare Corporation One Baxter Parkway, DF-3-2W Deerfield, IL 60015			EXAMINER MCCLELLAND, KIMBERLY KEIL	
			ART UNIT 1791	PAPER NUMBER
			MAIL DATE 04/23/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/811,589

Applicant(s)

TOMASETTI ET AL.

Examiner

KIMBERLY K. MCCLELLAND

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/23/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-16,18-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-16,18-22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sterile cassette must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 5-16, 18-22, and 24-28 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation in independent claims 1 and 18 of "the sheet not previously attached to either of the two sections of tubing prior to connecting of the sections" appears to be new matter. The mere absence of a positive recitation in the original specification is not basis for the exclusion of a feature. *Ex Parte Grasselli* 231 USPQ 393,394. (Bd. App. 1983). Consequently, this limitation is found to be new matter. Claims 2, 5-16, 19-22, and 24-28 are rejected due to dependency on independent claims 1 and 18.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2, 5-9, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of U.S. Patent No. 5,674,333 to Spencer.

6. With respect to claim 1, Yang et al. discloses a method for connecting flexible tubing wherein the tubing is placed in an axial end-to-end position (See Figures 2A and 2B), using a laser directed to heat the tube ends (paragraph 0068), positioning a sheet of material (i.e. drum head) between the axial surfaces of the tubing sections (See paragraph 0072), bringing the axially facing surfaces of the two tubing sections into engagement with the sheet, and directing the electromagnetic beam generally toward the tubing ends for welding the two sections of tubing together (paragraph 0071). Yang also discloses the sheet material is formed from a separate sheet of material (610) attached to the axial surface at the end of a tubing section, the sheet being formed of a material which absorbs energy of an electromagnetic beam; directing the electromagnetic beam onto the sheet for welding tubing sections together (See paragraphs 0072 and 0131-0139), and the sheet is not previously attached to either of the two tubing sections prior to connecting of the sections (i.e. end cap over vented seal; paragraph 0066). However, Yang et al. does not specifically disclose maintaining interior passages of the two tubing sections so as to be free from exposure to the surrounding environment until and during welding.

7. Spencer discloses an apparatus for welding together two sections of tubing, including a method of welding two tubing sections together and maintaining interior passages of the two tubing sections so as to be free from exposure to the surrounding

environment until and during welding (See Figures 5-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the tubing sections free from exposure to the environment until and during welding as taught by Spencer in the method of Yang et al. The motivation would have been to prevent contamination in the tubing or patient (column 5, lines 25-27).

8. As to claim 2, Yang et al. is silent as to the temperature of the tubing ends before the laser is activated. However, in order for the tubing to be in a solid state prior to the welding process, the temperature of the tubing ends must be below the melting temperature of the material forming the tubing section. Yang et al. discloses that the laser melts the tubing (paragraph 0069).

9. As to claim 5, Yang et al. discloses that the tubing material is substantially transparent (not laser responsive) to the electromagnetic beam (paragraph 0127).

10. As to claim 6, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071) and flow outward when heated (paragraph 0072).

11. As to claim 7, Yang et al discloses that dye may be applied to the tube ends (areas to be joined) that are welded by the laser (paragraph 0129).

12. As to claim 8, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071).

13. As to claim 9, Yang et al. discloses a method for connecting two pieces of tubing as disclosed above. Yang et al. also discloses that all the welding method is carried out in the axial position (See Figures 4A-4F). However, Yang does not disclose cutting off end portions of the tubing sections.

14. Spencer discloses an apparatus for welding together two sections of tubing, including a method of cutting of end sections of tubing prior to welding (column 3, lines 14-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of cutting the tubing sections prior to welding, as taught by Spencer, with the laser welding method of Yang et al. in the axial position in order to ensure proper connection during welding.

15. As to claim 16, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071), and flow outward (paragraph 0072).

16. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of U.S. Patent No. 5,674,333 to Spencer as applied to claims 1-2, 5-9, and 16 above, and further in view of U.S. Patent No 4,832,773 to Shaposka et al.

17. Yang et al., Spencer, and Savitski disclose a method of welding tubing sections together. Spencer also teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40). However, Yang et al., Spencer, and Savitski et al. do not disclose the clamping of the tubing.

18. As to claim 10, Shaposka et al. discloses a method for connecting sections of tubing, including clamping the cut (pre-cut) tubing sections (column 3, lines 48-51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of clamping the tubing sections, as taught by Shaposka et

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al., with the laser welding method of Yang et al. and Spencer to keep the tubing sections stationary.

19. As to claim 11, Yang et al. discloses sealing the tube ends prior to welding the tubing sections together (paragraph 0072).

20. As to claim 12, Yang et al. discloses the use of a weld block (drum head) to absorb energy from the laser and combine with the tube (paragraph 0072).

21. As to claim 13, Spencer teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40).

22. As to claim 14, Spencer teaches the movement of welded tubing (weld sample) from one location (device) to a remote location (vise column 3, line 62- column 4, line 12).

23. As to claim 15, Yang et al. discloses that all the welding method is carried out in the axial position (See Figures 4A-4F).

24. As to claim 23, Yang et al. discloses the step of providing material for absorbing energy comprises positioning a sheet of material between the axial surfaces of the of the tubing sections (See Yang et al. paragraph 0066), wherein the sheets are capable absorbing the energy of the electromagnetic beam (See Yang et al. paragraph 0072).

25. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of U.S. Patent No. 5,674,333 to Spencer as applied to claims 1-2, 5-9, and 16 above, and further in view of U.S. Patent No 4,948,062 to Mahar et al.

26. With respect to claim 25, Yang et al. does not specifically disclose extending the sheet of material between a supply roll and a take-up roll.

27. Mahar et al. discloses a method of dispensing film, including extending a sheet of material between a supply roll and a take-up roll (see Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the supply and take-off roll dispensing method taught by Mahar et al. with the sheet material of Yang et al. The motivation would have been to dispense the sheet material without twisting or the formation of knots.

28. As to claim 26, Yang et al. does not specifically disclose housing the supply roll in a sterile cassette.

29. Mahar et al. discloses a method of dispensing film, including housing the supply roll in a sterile cassette (17; see Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the sterile dispensing housing roll taught by Mahar et al. with the sheet material of Yang et al. The motivation would have been to prevent contamination of the sheet material.

Allowable Subject Matter

30. Claims 18-22, 24, and 27-28 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action.

31. The following is a statement of reasons for the indication of allowable subject matter:

32. The prior art of record neither discloses nor suggests the steps of sealing a clamped tubing section with an absorption member in a collapsed configuration through electromagnetic radiation, removing the absorption member, and welding two tubing sections together through a separate intermediate sheet placed on the axially facing surfaces of the tubing sections with electromagnetic radiation. The closest prior art of record, U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. discloses many features of the claimed connecting method, but does not disclose or fairly suggest the step of removing the absorption member, nor is there any obvious reason to do so. Consequently, claims 18-22, 24, and 27-28 are found to distinguish over the prior art.

Response to Arguments

33. Applicant's arguments filed 02/23/09 have been fully considered but they are not persuasive.

34. In light of the amendment to the claims, claims 1-2, 5-16, 18-22, and 24-28 have been rejected under 35 U.S.C. 112, first paragraph.

35. With respect to applicant's arguments that Yang exclusively discloses a film which has already been sealed onto a tubing end, this argument is not persuasive. The limitation in independent claims 1 and 18 of "the sheet not previously attached to either of the two sections of tubing prior to connecting of the sections" appears to be new matter. The mere absence of a positive recitation in the original specification is not basis for the exclusion of a feature. *Ex Parte Grasselli* 231 USPQ 393,394. (Bd. App.

1983). Consequently, this limitation is found to be new matter. Also, the embodiment taught by Yang of a drum head sealed over a vented seal would result in a sheet material that was not previously connected to either tubing section (see paragraph 0066). "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Therefore, the alternative embodiment taught by Yang reads on the currently claimed invention.

36. Applicant's remaining arguments are drawn to the dependency claims 2, 5-16, and 25-26 on independent claim 1. These arguments are not persuasive for the reasons noted above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KIMBERLY K. MCCLELLAND whose telephone number is (571)272-2372. The examiner can normally be reached on 8:00 a.m.-5 p.m. Mon-Thr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Philip C. Tucker can be reached on (571)272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. K. M./
Examiner, Art Unit 1791

KKM

/Philip C Tucker/
Supervisory Patent Examiner, Art Unit 1791